

### REMARKS

Claims 13-15, 17-18 and 20-24 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Carling (WO 93/11773). Claims 16 and 19 remain rejected as being unpatentable over Carling in view of Hett et al. and Ryrefeldt et al.

Applicant respectfully requests that these rejections be withdrawn.

In Applicant's previous response, Applicant explained that there is no recognition in the Carling reference that the budesonide/formoterol compositions described therein would be suitable for use on an "as needed" basis, much less that their use in this manner would be advantageous. Instead, Carling states that "the intended dose regimen is a twice daily administration," which is in keeping with general clinical practice and many clinical guidelines, which recommend only an entirely different class of drugs, short-acting inhaled  $\beta_2$ -agonists, for acute therapy. Applicant further noted that the secondary references do not supply a teaching or suggestion of the use of budesonide/formoterol compositions on an "as needed" basis. Instead, these references are cited to provide teachings that (R,R)-formoterol and the 22R epimer of budesonide are particularly potent forms of formoterol and budesonide.

The Examiner states, in the present office action, that these arguments are not persuasive because the phrase "as needed" could encompass the "twice daily" regimen described by Carling. In response to this statement, Applicant has amended claim 13 to recite that inhalation is "on demand, as determined by the patient based on the patient's symptoms."

Applicant agrees, *arguendo*, that a particular patient might determine that he or she needs to inhale the claimed asthma medication twice on a particular day. However, when, as claimed, the frequency of inhalation is determined by the patient, based on the patient's symptoms, on other days the same patient would in all probability inhale the medication more or less frequently than twice a day.

Carling provides no teaching or suggestion of the claimed patient-determined mode of administration. Carling's twice daily regimen is prescribed by the physician, rather than determined by the patient, and is fixed, rather than variable based on the symptoms experienced by the patient on a given day.

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Accordingly, Applicant respectfully submits that the claims are patentable over these references.

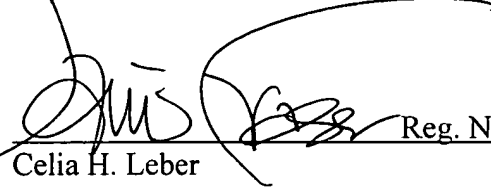
Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be allowed. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date:

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**Version with markings to show changes made**

In the claims:

Claim 13 has been amended as follows:

13. A method of prevention or treatment of an acute condition of asthma and/or intermittent asthma and/or episodes in chronic asthma, which comprises  
instructing a patient to inhale, [as needed] on demand, as determined by the patient based on the patient's symptoms, to provide short-term symptomatic relief of asthma symptoms, an effective amount of a composition comprising, in admixture:
- (a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and
  - (b) a second active ingredient which is budesonide.